DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

11/25/97 12/1/97 AEW

684

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-07

November 14, 1997

Joe Rodriguez, President
Advanced Respiratory Care
7350 Northwest 7th Street
Miami, Florida 33126

Dear Mr. Rodriguez:

Inspection of your medical gas filling operation on October 9 & 14, 1997, by FDA Investigator Jennifer M. Donzanti, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed and liquid medical Oxygen USP causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk oxygen received to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders and cryogenic vessels of compressed and liquid medical Oxygen USP are not being tested for purity prior to release for distribution. The [redacted] Oxygen Analyzer used by your firm is not an acceptable test device for oxygen purity in that the device is not equivalent to the USP test accuracy of ± 0.1%

You have failed to established and/or maintain written procedures for all production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, written procedures for the filling and testing of compressed medical oxygen are incomplete and are not maintained. No written procedures are established for the receipt and acceptance of incoming bulk oxygen, filling and testing of liquid medical oxygen, completion of batch production records, calibration and maintenance of equipment, labeling, quarantine procedures, handling of complaints, employee training, or supervision.

Batch production and control records are not maintained documenting that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. Unique lot numbers are not assigned to filled cylinders of compressed medical oxygen produced from each uninterrupted filling sequence, and records documenting calibration and maintenance of equipment are not maintained.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm reveals the products to be misbranded within the meaning of Sections 502(b)(1) and 502(b)(2) of the Act in that labels fail to bear the place of business of your firm, and an accurate statement of the quantity of contents. With respect to the 502(b)(2) violation, the contents of cylinders may be expressed in terms of the available volume of Oxygen USP in liters at 70° F (21.1° C) and one atmosphere.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

Michael A. Chappell
Acting Director
Florida District